

Claims

1. A kit comprising a balloon catheter comprising a balloon at or near its distal end, and a stent mounted on the balloon, characterized in that in that the exterior surface of the balloon and stent are provided with a coherent coating comprising a film-forming polymer.

2. A kit according to claim 1 in which the coating is continuous around the circumference of the exterior surface of the balloon and stent over at least a portion of the axial extent of that section.

3. A kit according to claim 1 or claim 2 in which the coating extends along the entire axial length of the stent, preferably beyond both ends thereof.

4. A kit according to any preceding claim in which the polymer of the coating is cross-linked.

5. A kit according to any preceding claim in which the polymer has pendent zwitterionic groups.

6. A kit according to claim 5 in which the polymer is formed from ethylenically unsaturated monomers including a zwitterionic monomer of the general formula I:

YBX

I

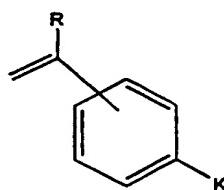
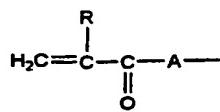
20 wherein

B is a straight or branched alkylene (alkanediyl), alkyleneoxaalkylene or alkylene oligo-oxaalkylene chain optionally containing one or more fluorine atoms up to and including perfluorinated chains or, if X or Y contains a terminal carbon atom bonded to B, a valence bond;

25 X is a zwitterionic group; and

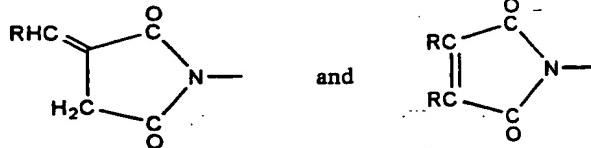
Y is an ethylenically unsaturated polymerisable group selected from

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$\text{CH}_2=\text{C}(\text{R})-\text{CH}_2-\text{O}-$, $\text{CH}_2=\text{C}(\text{R})-\text{CH}_2\text{OC(O)}-$, $\text{CH}_2=\text{C}(\text{R})\text{OC(O)}-$, $\text{CH}_2=\text{C}(\text{R})-\text{O}-$,
 $\text{CH}_2=\text{C}(\text{R})\text{CH}_2\text{OC(O)N(R')-}$, $\text{R}^2\text{OOCCR=CRC(O)-O-}$, $\text{RCH}=\text{CHC(O)O}-$,
 $\text{RCH}=\text{C(COOR')CH}_2-\text{C(O)-O-}$,

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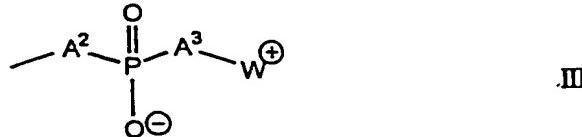
and

wherein:

R is hydrogen or a C₁-C₄ alkyl group;10 R¹ is hydrogen or a C₁-C₄ alkyl group or R¹ is -B-X where B and X are as defined above; andR² is hydrogen or a C₁₋₄ alkyl group;A is -O- or -NR¹-;K is a group -(CH₂)_pOC(O)-, -(CH₂)_pC(O)O-,15 -(CH₂)_pOC(O)O-, -(CH₂)_pNR³-, -(CH₂)_pNR³C(O)-,
-(CH₂)_pC(O)NR³-, -(CH₂)_pNR³C(O)O-, -(CH₂)_pOC(O)NR³-,
-(CH₂)_pNR³C(O)NR³- (in which the groups R³ are the same or different),
-(CH₂)_pO-, -(CH₂)_pSO₃-, or, optionally in combination with B, a valence bond p is from 1 to 12; and20 R³ is hydrogen or a C₁-C₄ alkyl group.

7. A kit according to claim 6 in which X is a group having the general formula III

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in which the moieties A² and A³, which are the same or different, are -O-, -S-, -NH- or a valence bond, preferably -O-, and W⁺ is a group comprising an ammonium, phosphonium or sulphonium cationic group and a group linking the anionic and cationic moieties which is preferably a C₁₋₁₂-alkanediyi group,

preferably in which W⁺ is a group of formula

-W¹-N⁺R⁹₃, -W¹-P⁺R¹⁰₃, -W¹-S⁺R¹⁰₂ or -W¹-Het⁺ in which:

W¹ is alkanediyl of 1 or more, preferably 2-6 carbon atoms optionally containing one or more ethylenically unsaturated double or triple bonds, disubstituted-aryl (arylene), alkylene arylene, arylene alkylene, or alkylene aryl alkylene, cycloalkanediyl, alkylene cycloalkyl, cycloalkyl alkylene or alkylene cycloalkyl alkylene, which group W¹ optionally contains one or more fluorine substituents and/or one or more functional groups; and

either the groups R⁹ are the same or different and each is hydrogen or alkyl of 1 to 4 carbon atoms, preferably methyl, or aryl, such as phenyl, or

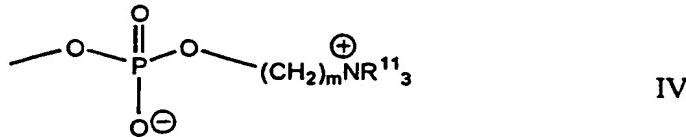
two of the groups R⁹ together with the nitrogen atom to which they are attached form an aliphatic heterocyclic ring containing from 5 to 7 atoms, or the three groups R⁹ together with the nitrogen atom to which they are attached form a fused ring structure containing from 5 to 7 atoms in each ring, and optionally one or more of the groups R⁹ is substituted by a

hydrophilic functional group, and

the groups R¹⁰ are the same or different and each is R⁹ or a group OR⁹, where R⁹ is as defined above; or

Het is an aromatic nitrogen-, phosphorus- or sulphur-, preferably nitrogen-, containing ring, for example pyridine.

8. A kit according to claims 7 in which X is a group having the general formula IV:

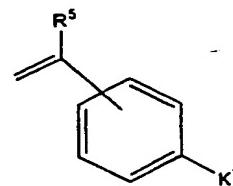
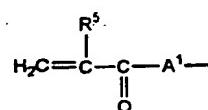


where the groups R¹¹ are the same or different and each is hydrogen or C₁₋₄ alkyl, and m is from 1 to 4, in which preferably the groups R¹¹ are the same preferably methyl.

9. A kit according to any of claims 4 to 9 in which the monomers used to form the polymer include a surface binding monomer having the general formula II

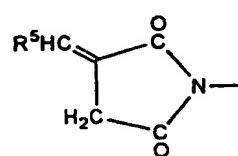
Y^1R^4

II

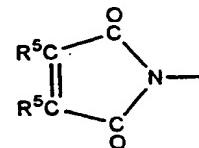
wherein Y^1 is selected from

10 $CH_2=C(R^5)-CH_2-O-$, $CH_2=C(R^5)-CH_2-OC(O)-$, $CH_2=C(R^5)OC(O)-$, $CH_2=C(R^5)-O-$,
 $CH_2=C(R^5)CH_2OC(O)N(R^6)-$, $R^7OOCR^5=CR^5C(O)-O-$,
 $R^6CH=CHC(O)O-$, $R^5CH=C(COOR')CH_2-C(O)-O-$,

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and



wherein:

- R^5 is hydrogen or a C_1-C_4 alkyl group;
- R^6 is hydrogen or a C_1-C_4 alkyl group or R^6 is R^4 ;
- R^7 is hydrogen or a C_{1-4} alkyl group;
- 20 A^1 is $-O-$ or $-NR^6-$; and
- K^1 is a group $-(CH_2)_qOC(O)-$, $-(CH_2)_qC(O)O-$,
 $-(CH_2)_qOC(O)O-$, $-(CH_2)_qNR^8-$, $-(CH_2)_qNR^8C(O)-$,
 $-(CH_2)_qC(O)NR^8-$, $-(CH_2)_qNR^8C(O)O-$, $-(CH_2)_qOC(O)NR^8-$,
 $-(CH_2)_qNR^8C(O)NR^8-$ (in which the groups R^8 are the same or different),
 $-(CH_2)_qO-$, $-(CH_2)_qSO_3-$, or a valence bond
- 25 q is from 1 to 12;
- and R^8 is hydrogen or a C_1-C_4 alkyl group;
- and R^4 is a surface binding group, selected from hydrophobic groups, ionic groups, reactive groups capable of forming covalent bonds with surface functional groups on the surface of the tube and crosslinkable groups capable of forming intermolecular crosslinks, optionally in conjunction with curing agents.

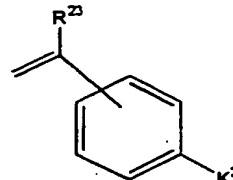
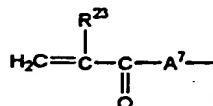
10. A kit according to any of claims 4 to 9 in which the polymer is formed from ethylenically unsaturated monomers including a monomer of formula VIII



VIII

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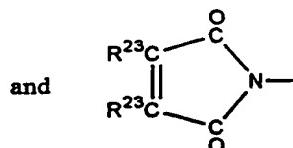
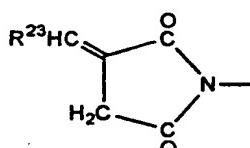
wherein

 Y^2 is selected from

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$CH_2=C(R^{23})-CH_2-O-$, $CH_2=C(R^{23})-CH_2 OC(O)-$, $CH_2=C(R^{23})OC(O)-$,
 $CH_2=C(R^{23})-O-$, $CH_2=C(R^{23})CH_2OC(O)N(R^{24})-$, $R^{25}OOCCR^{23}=CR^{23}C(O)-O-$,
 $R^{23}CH=CHC(O)O-$, $R^{23}CH=C(COOR^{25})CH_2-C(O)-O-$,

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wherein:

20 R^{23} is hydrogen or a C_1-C_4 alkyl group; R^{24} is hydrogen or a C_1-C_4 alkyl group or R^{24} is $R^{30} Q^1$; R^{25} is hydrogen or a C_{1-4} alkyl group; A^7 is $-O-$ or $-NR^{24}-$; and K^2 is a group $-(CH_2)_tOC(O)-$, $-(CH_2)_tC(O)O-$,25 $-(CH_2)_tOC(O)O-$, $-(CH_2)_tNR^{28}-$, $-(CH_2)_tNR^{28}C(O)-$, $-(CH_2)_tC(O)NR^{28}$, $-(CH_2)_tNR^{28}C(O)O-$, $-(CH_2)_tOC(O)NR^{28}-$, $-(CH_2)_tNR^{28}C(O)NR^{28}-$ (in which the groups R^{28} are the same or different), $-(CH_2)_tO-$, $-(CH_2)_tSO_3-$, or a valence bond

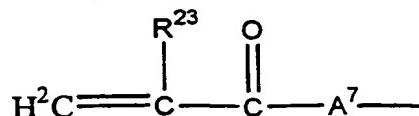
t is from 1 to 12;

30 and R^{28} is hydrogen or a C_1-C_4 alkyl group;

R^{30} is a straight or branched C_{2-24} alkanediyl group, or a alkyleneoxaalkylene or alkylene(oligo-oxaalkylene) group in which each alkylene has 2 to 12 carbon atoms, and

Q¹ is a group $Si(OR^{26})_3$ in which the groups R²⁶ are independently selected from C_{1-4} alkyl groups.

5 11. A kit according to claim 10 in which Y² is



10 in which R²³ is preferably methyl, and A⁷ is preferably -O-, and in which R³⁰ is C_{2-6} alkanediyl and each R²⁶ is C_{1-2} -alkyl, preferably methyl.

12. A kit according to any preceding claim which is sterile, preferably sterilised by ethylene oxide treatment.

13. A kit according to any preceding claim in which the luminal surface of the guidewire lumen has not been provided with the said coherent coating.

14. A kit according to any preceding claim in which the stent is formed from a metal tube, preferably of stainless steel.

15. A method in which an assembly comprising a balloon catheter and, mounted on the balloon of the balloon catheter, a stent is coated with a liquid coating composition containing a film-forming polymer, and the coating composition is then cured to leave a coherent film of polymer on the exterior surface of the stent and balloon.

20 16. A method according to claim 15 in which in the coating step the balloon and stent assembly is dipped into the liquid composition.

25 17. A method according to claim 16 in which the catheter has a guidewire lumen passing through the balloon and the lumen is blocked during the dipping step.

18. A method according to any of claims 15 to 17 in which curing involves removal of solvent from the coating composition, preferably by evaporation.

19. A method according to claim 18 in which the solvent in the coating composition comprises water, alcohol, ether, or alkane or mixtures, preferably ethanol in admixture with water or alkane.

5 20. A method according to any of claims 15 to 19 in which the film-forming polymer is cross-linkable and the curing step includes a step of cross-linking the polymer.

21. A method according to claim 20 in which the polymer is as defined in claim 10 or claim 11.

22. A method according to any of claims 15 to 21 in which the coated 10 assembly is sterilised by contact with ethylene oxide.